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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,702	07/20/2001	Andrei W. Konradi	002010-680	2073

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 02/05/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,702

Applicant(s)

KONRADI ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, and 11-16 is/are rejected.
- 7) ☒ Claim(s) 8-10, and 17-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of species of formula (group) IIc in paper #8 is acknowledged. Claims 1-21 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-7, and 11-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claim 1 recites "and pharmaceutically acceptable salts", which suggests a mixture of compounds and salts. Hence, said claim is ambiguous because it appears to claim a composition as well. Applicant is advised to replace 'and' with 'or'.
- b. Claims 1 and 11, recite the phrase "with 1 to 3 substituents selected from the group consisting of with one or two substituent(s) selected from the group consisting of..." (see definitions of B and C). It is unclear how many substituents are intended.
- c. Claims 2 and 13 recite the phrase "further the wherein", which seems incomplete.
- d. Claims 2-5 lack antecedent basis because they recite "alkenyloxy" and/or "substituted alkenyloxy" [as a substituent for ring B], which are not recited in claim 1.

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e. Claim 11 recites the phrase “in addition to ring B or C,...” but ring C does not appear in formulae IIa – IIe. Thus, it is unclear as to the relationship of ring C with formulae IIa – IIe.

f. Claims 13-16 lack antecedent basis because they recite “alkenyloxy” and/or “substituted alkenyloxy” [as a substituent for ring B], which are not recited in claim 11.

g. Claims 6, 7, and 12 are rejected as being dependent on claim 1 or 11, and carrying over the limitations of claim 1 or 11.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 4-7, 11, 12, 15, and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds with ring B or C as a monocycle (i.e., pyridone or pyrimidone), does **not** reasonably provide enablement for compounds with ring B or C as a **bicycle or tricycle** (i.e., fused pyridone or fused pyrimidone).

The following factors have been considered in the determination of an enabling disclosure:

- (1) The quantity of experimentation necessary;
- (2) The amount of direction or guidance presented;

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- (3) The state of the prior art;
- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The breadth of the claims;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification does not provide a generic teaching to make compounds with ring B or C as a fused ring. It does not disclose how the starting material for a fused pyridone or fused pyrimidone can be made or obtained. Only species having B or C as pyridone or pyrimidone are disclosed. State of the art, **Head et. al.** WO 99/37618, does not provide preparation for compounds of fused pyridone or fused pyrimidone, nor does it relate said compounds to the inhibition of VLA-4. Therefore, given the unpredictable nature of the art, and limited guidance provided, one skilled in the art will have to carry out undue experimentation to make and use the claimed compounds with ring B or C as a fused ring.

Regarding enablement for chemical cases, the M.P.E.P. explicitly states that:

...in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F. 2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most **chemical reactions** and **physiological activity**, more may be required. *In re Fisher*, 427

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F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)...See also In re Wright, 999 F.2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 496, 20 USPQ 2d 1438, 1445 (Fed. Cir. 1991).

This is because it is **not obvious** from the disclosure of one species, what other species will work. {M.P.E.P. 2164.03}

Also, as has been ruled by the court in *Genetech Inc. v. Novo Nordisk*, failure to disclose any specific starting material or any condition for preparation constitutes lack of enablement, and relying on the knowledge of one skilled in the art cannot cure such deficiency in enablement (*Genetech Inc. v. Novo Nordisk*, 108 F.3d 1361, 42 USPQ 2d 1001 (Fed. Cir. 1997)).

Claim Objections

3. Claims 8-10, and 17-21 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to precedent claims in the alternative only, and must not depend on another multiple dependent claim either directly or indirectly. See MPEP § 608.01(n). Accordingly, the claims 8-10, and 17-21 have not been further treated on the merits.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Tamthom N. Truong
Examiner
Art Unit 1624

February 4, 2003